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October 12, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 92N-0297

Dear Sir or Madam:

On behalf of the International Warehouse Logistics Association (IWLA), I request the opportunity to testify at the October 27 hearing being held on certain requirements of the final rule implementing the Prescription Drug Marketing Act.

We request 10 minutes to present our testimony at the hearing. The testimony will address the need for a modification to the regulations to clearly state that the provisions are not applicable to a public warehouse because a public is not a wholesale distributor for purposes of the PDMA. Absent this modification, a public warehouse could be wrongfully referred to as either an "authorized distributor" or an "unauthorized distributor." Neither term is correct, as a public warehouse is not a wholesaler distributor in any sense of the word.

The need for the modification is underscored by §203.50(d), which requires a manufacturer to "maintain a current written list of all authorized distributors of record", and to "make its list of authorized distributors of record available on request to the public for inspection or copying." These requirements confer on the manufacturer the ability to unilaterally determine that a public warehouse is a wholesale distributor and subject to the requirements for an "authorized distributor."

Thank you.

Sincerely,

Patrick C. O'Connor
Washington Representative
IWLA

92N-0297

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